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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/979,558	MARUYAMA ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *2-7 and 10-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 9/28/05. Claims 2, 3, 5, 7, 10, 13, 16, and 18 have been amended and claims 19-23 have been added. Claims 1-23 are pending, claims 8-9 are drawn to a non-elected invention. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Applicant's remarks are addressed following the statement of the rejections. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This action is **final.**

2. Applicant is advised that should claim 2 or claim 3 be found allowable, claim 4 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The intended use recited in claim 4 does not appear to further limit claim 2 or claim 3 since independent claim 2 already recites that the claimed probe "allows for species specific detection or identification of one or more microorganisms selected from Psychrobacter pacificensis and/or Psychrobacter glacincola" and the language of claim 4 appears to be a substantial duplicate of this language.

Claim Rejections - 35 USC § 112

3. Claims 3, 4, 7, 16, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In these claims, it is unclear how the preamble of the claims is accomplished by the practice of the method steps of the claim. The preamble of the claims recites a method for specifically detecting or identifying a bacterium belonging to P. pacificensis, yet the method steps of the claim recite the use of a probe which allows for species specific identification of "one or more" of P. pacificensis and P. glacincola. It is not clear how, if one uses a probe that is specific for P. glacincola alone or both species how one would accomplish species-specific detection or identification of P. pacificensis.

Claims 3 and 4 are indefinite over the recitation "wherein the nucleotide sequence of the oligonucleotide probe comprises the base sequence of SEQ ID NO: 2" because SEQ ID NO: 2 does not consist of a fragment of SEQ ID NO: 1, it consists of a fragment of the complement of SEQ ID NO: 1, which is not recited in claim 2, and therefore it is not clear how an molecule can meet both the requirements of claim 2 and claims 3 and 4.

4. Claims 2, 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid probes which comprise instant SEQ ID NO: 1 in its entirety and which comprise instant SEQ ID NO: 2 or nucleotides 458-476 of SEQ ID NO: 1 (which are the complement of SEQ ID NO: 2), as probes which "allow for species specific detection or identification of selected from Psychrobacter pacificensis and Psychrobacter glacincola," and methods which use such probes, does not reasonably provide enablement for oligonucleotides or methods for using oligonucleotides comprising other fragments of instant SEQ ID NO: 1 wherein the oligonucleotides allow for species specific detection or identification of one or more

microorganisms selected from Psychrobacter pacificensis and/or Psychrobacter glacincola. Further, the specification does not provide enablement for the idea that any particular fragment of SEQ ID NO: 1 or the complement of SEQ ID NO: 1 can be used to distinguish P. pacifensis from P. glacincola, as encompassed by the intended use statements of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims as written are subject to a number of interpretations, as the language used in the claims is broad. This rejection is written against an interpretation of "allows for species-specific detection or identification" which means that the recited oligonucleotides must be "unique to" and/or would detect only the recited Psychrobacter pacificensis and/or Psychrobacter glacincola, and for claims 6 and 19, would only detect P. pacificensis. This is one possible interpretation of the claims. A broader interpretation is addressed in the art rejections.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (*MPEP* 2164.01(a)).

Claims 2, 4, 6, 10, 11, 12, 20, 21, 22 and 23 are drawn to oligonucleotide probes that consist of any "part of the base sequence of SEQ ID NO: 1, wherein the probe allows for

species-specific detection and/or identification of one or more microorganisms selected from Psychrobacter pacificensis and/or Psychrobacter glacincola" Claims 5, 7, and 14-19 are drawn to methods in which such a probe is employed in "detecting or identifying at least one bacterium selected from" *P. pacificensis*, *P. glacincola*, (claim 5) or in "specifically detecting or identifying a bacterium belonging to" *P. pacificensis* (claim 7). These claims further require that the "the probe allows for species-specific detection and/or identification of one or more microorganisms selected from Psychrobacter pacificensis and/or Psychrobacter glacincola."

The specification teaches instant SEQ ID NO: 1 which is disclosed as being the 16s rRNA gene from Psychrobacter pacificensis strain NIBH P2K6 (p. 2, lines 15-16). This sequence is 1526 base pairs in length. Instant SEQ ID NO: 1 in its entirety appears to be unique to Psychrobacter pacificensis strain NIBH P2K6 based on a sequence search of the art. The most closely related sequence identified was from P. pacificensis strain NIBH P2K18 (alignment provided with office action mailed 5/12/05). The specification further teaches instant SEQ ID NO: 2, which is a fragment of SEQ ID NO: 1 and which is demonstrated in the specification as succeeding in the species specific detection of P. pacificensis and P. glacincola (Example 4). Example 5 demonstrates that under high stringency conditions that do not allow for mismatches, instant SEQ ID NO: 2 hybridizes to all five strains of P. pacificensis, but not the tested P. glacincola sample.

In order to determine which portions of instant SEQ ID NO: 1 would be "unique" to this P. pacificensis and/or P. glacinocola, or both, one must be able to compare instant SEQ ID NO: 1 to the 16S rDNA sequence from closely related species of organisms. In the instant specification no guidance is given as to the sequence of this gene form other Psychrobacter species. At the

time the invention was made, the closes prior art over the full length SEQ ID NO: 1 was the 16s ribosomal RNA gene partial sequence from P. glacincola as disclosed in GenBank record U85876 which had 87% identity over the full length SEQ ID NO: 1 and 95.9% local identity when nucleotides 30-1498 of SEQ ID NO: 1 were compared to nucleotides 12-1481 of the record (see enclosed Sequence Alignment (1) provided with office action mailed 5/12/05). This sequence has a mismatch with instant SEQ ID NO: 2. However, the prior art also teaches a different fragment of the P. glacincola 16S rDNA in GenBank record AF025555, and this record comprises SEQ ID NO: 2 in its entirety. Thus, it appears that under some circumstances instant SEQ ID NO: 2 and the complement of SEQ ID NO: 2 would hybridize to both species, and would not be useful for the species specific detection of either. The entire fragment taught in this second record shares 99% identity with nucleotides 210-508 of instant SEQ ID NO: 1, differing only by the insertion of a single nucleotide over the full length sequence (see enclosed Sequence Alignment (2) provided with office action mailed 5/12/05). Thus, though the P. glacinola sample tested in the specification was not detected under high stringency conditions, the P. glacinola sample used to obtain the nucleic acid disclosed in this record would be detected by instant SEQ ID NO: 2. Thus, even applicant's most preferred oligonucleotide would not be expected to be specifically detect only P. pacificensis under even high stringency conditions. The sequence of the 16S rDNA genes of additional strains of P. pacificensis were not known in the prior art at the time of filing of the instant invention.

Further, at the time the invention was made, there were a wide variety of nucleic acid probes know that were fragments of SEQ ID NO: 1, but which were taught in the prior art as being useful for the detection of other species of organisms. For example Leckie et al. (US

5631130) teach a probe (their SEQ ID NO: 65) which is a fragment of SEQ ID NO: 1 for the detection of Mycobacterium. There is no guidance in the specification as to which portions of SEQ ID NO: 1, other than SEQ ID NO: 2 would be useful for species-specific detection or identification of *P. pacificensis* and/or *P. glacincola.*

It is unpredictable as to whether one of skill in the art could make and use applicants' invention in a manner reasonably commensurate with the instant claims. The specification exemplifies the successful use of a single subsequence of SEQ ID NO: 1, SEQ ID NO: 2, in the detection (as well as the differentiation) of *P. pacificensis* and *P. glacincola* (see entire specification, particularly Examples 3-5). However, as discussed previously, instant SEQ ID NO: 2 is also disclosed in the prior art as being within at least strain MED12 of P. glacincola, and thus SEQ ID NO: 2 would be expected to detect this strain as well. The instant claims are sufficiently broad so as to encompass probes comprising any subsequence of any length selected form SEQ ID NO: 1 that is "allows species specific detection" of *P. pacificensis* and/or *P. glacincola* and the use of any such probe in the detection of not only *P. pacificensis* and/or *P. glacincola*. Some claims recite that the probes are specific for only P. pacificensis. The specification only exemplifies the successful detection of two particular species (*P. pacificensis* and *P. glacincola*) with a single species of probe (SEQ ID NO: 2). The specification does not identify or provide guidance for the identification of any nucleic acid fragment of instant SEQ ID NO: 1 that is specific (i.e. unique) to P. pacificensis, nor does the specification identify any additional probes that are specific to only the two species and not any other species. Lacking guidance from the specification, one of skill in the art may look to the teachings of the prior art for further guidance and enablement of a claimed invention. In the instant case, the prior art as

exemplified by Bowman et al (Applied and Environmental Microbiology 63(8):3068-3078 [8/1997]) teaches the use of a universal primer sharing regions of identify with SEQ ID NO: 1 in detection of *P. glacincola*, but does not begin to provide the sequences of the 16S rDNA gene from closely related microorganisms that would be necessary for comparison in order to determine the regions of SEQ ID NO: 1 that are would allow species specific detection of *P. pacificensis* and/or *P. glacincola*. Neither the teachings of the specification nor of the art enable the identification or use of the of probes encompassed by the claims in identification of *P. pacificensis*, *P. glacincola* wherein "species-specific identification and/or detection" of the species means that the sequence is unique to or would hybridize to only the species recited in the claims. While it is clearly within the ability of one of skill in the art to conduct further experimentation aimed at identifying additional subsequences of SEQ ID NO: 1 that may be useful in specific identification of *P. pacificensis* and/or *P. glacincola*, the outcome of such experimentation cannot be predicted, and more specifically, which of the subsequences of SEQ ID NO: 1 that are "specific" to the individual strain P2K6 are entirely unpredictable. Accordingly, it is unpredictable as to whether any quantity of experimentation would result in the identification of any other species that may actually be used successfully in the methods disclosed by applicants.

There can be no doubt from the teachings of the specification that applicant could have made any possible fragment of SEQ ID NO: 1, given the full length nucleotide sequence of this molecule, using standard molecular biology techniques at the time the invention was made. However, given the teachings of the specification, it is entirely unpredictable which of those fragments would be allow species-specific detection or identification of *P. pacificensis* and/or *P.*

glacincola when "species-specific" is interpreted to mean that recited oligonucleotide is unique to or would hybridize only to nucleic acids from these species. Applicant has not given a single example of a fragment of SEQ ID NO: 1 that would meet this requirement. Accordingly, with respect to the requirement that the probes claimed and used in the methods recited herein comprise a part of SEQ ID NO: 1 that allows species species-specific detection or identification of *P. pacificensis* and/or *P. glacincola*, and insofar as this requirement is intended to mean that the probes are unique to or would hybridize only to these species, it would require undue experimentation to make and use applicants' invention in a manner reasonably commensurate with the instant claims.

Claim Rejections - 35 USC § 102

5. Claims 2, 4, 6, 11, 12, 20, are 21 rejected under 35 U.S.C. 102(b) as being anticipated by Leckie et al. (US 5631130).

Leckie et al. teach an purified oligonucleotide probe which consists of part of the base sequence of SEQ ID NO: 1. Specifically, SEQ ID NO: 65 taught by Leckie et al. is identical to nucleotides 956-975 of instant SEQ ID NO: 1. The probe taught by Lecke et al. is 20 nucleotides in length and is labeled with either biotin or fluorescein (Col.20, lines 66-67). Regarding the functional language set forth in the claims, this art rejection is applied to a broadly interpreted claim wherein the probe taught by Leckie et al. would "allow" for species specific detection or identification of the recited bacteria in a culture, for example where this bacteria is the only expected bacteria, or it would allow for such detection or identification in an assay in

conjunction with other oligonucleotide fragments of SEQ ID NO: 1, for example as a primer pair.

6. Claims 2, 4, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Abrams et al (US 6238927).

Abrams et al. teach an purified oligonucleotide probe which consists of part of the base sequence of SEQ ID NO: 1. Specifically, SEQ ID NO: 1 taught by Abrams et al. is identical to nucleotides 923-974 of instant SEQ ID NO: 1. Regarding the functional language set forth in the claims, this art rejection is applied to a broadly interpreted claim wherein the probe taught by Abrams et al. would "allow" for species specific detection or identification of the recited bacteria in a culture, for example where this bacteria is the only expected bacteria, or it would allow for such detection or identification in an assay in conjunction with other oligonucleotide fragments of SEQ ID NO: 1, for example as a primer pair.

7. Claims 2, 4, 6, 11, 20, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Leong (US 5635348).

Leong teaches a purified oligonucleotide probe which consists of part of the base sequence of SEQ ID NO: 1. Specifically, SEQ ID NO: 8 taught by Leong et al. is identical to nucleotides 1358-1384 of instant SEQ ID NO: 1. The probe taught by Leong et al. is 27 nucleotides long and is attached to a label which is an isotope (see Example 6, Col. 16). Regarding the functional language set forth in the claims, this art rejection is applied to a broadly interpreted claim wherein the probe taught by Leong would "allow" for species specific detection or identification of the recited bacteria in a culture, for example where this bacteria is the only expected bacteria, or it would allow for such detection or identification in an assay in

conjunction with other oligonucleotide fragments of SEQ ID NO: 1, for example as a primer pair.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leckie et al. (5631130).

Leckie et al. teach an purified oligonucleotide probe which consists of part of the base sequence of SEQ ID NO: 1. Specifically, SEQ ID NO: 65 taught by Leckie et al. is identical to nucleotides 956-975 of instant SEQ ID NO: 1. The probe taught by Lecke et al. is 20 nucleotides in length and is labeled with either biotin or fluorescein (Col.20, lines 66-67). Regarding the functional language set forth in the claims, this art rejection is applied to a broadly interpreted claim wherein the probe taught by Leckie et al. would "allow" for species specific detection or identification of the recited bacteria in a culture, for example where this bacteria is the only expected bacteria, or it would allow for such detection or identification in an assay in conjunction with other oligonucleotide fragments of SEQ ID NO: 1, for example as a primer pair.

Leckie et al. do not teach a probe wherein the label is one of those listed in claims 22 or 23. Each of the labels recited in the claims is a label that was routinely used in molecular biology detection assays at the time the invention was made. Leckie et al. teach that a variety of

different labels can be used (see for example, Col. 10, lines 34-63). It would have been prima facie obvious to one of ordinary skill in the art to have modified the teachings of Leckie et al. so as to have used any known label for the identification and detection of products in solution.

Response to Remarks

A note is made regarding claims 22 and 23. In claims 21, from which these depend, it is set forth that the label is selected from an isotope, fluorescent colorant, and hapten. Claims 22 and 23 further define choices for the fluorescent colorant or the hapten, but they do not require in either claim that the label is required to be either the fluorescent label or the hapten. If applicant intends in claim 22, for example, to require that the label is a fluorescent colorant and that the colorant is selected from those listed, applicant should state as much. For example, "wherein the label is a fluorescent colorant selected from..." or similar language would accomplish this end.

Previously set forth 112 2nd rejections are moot in view of the amended claims. New 112 2nd rejections are set forth to address the amended claims.

With regard to the scope of enablement rejection, this rejection has been modified to address the amendments to the claims. Nonetheless, applicant's remarks are addressed insofar as they might be relevant to the instant rejection. Applicants state that they have removed the term "specific" from the rejected claims. This is not entirely accurate as applicants have included in the new claims that "species-specific" detection or identification is allowed. The claims as they are currently written are subject to at least two reasonable interpretations within the breadth of the claims. These are addressed in this office action under both 112 1st paragraph (a narrow interpretation) and under the prior art (a much broader interpretation). Both interpretations are

addressed in the rejections. Applicants state at page 11 of the response that they have amended the claims to overcome the scope of enablement rejection. This is not persuasive for the reasons set forth in the rejection in this office action.

The previous rejections under 102 are overcome by amendment. New rejections are set forth to address the amended claims.

Applicant's remarks regarding claims 3 and 10 applicants remarks addressing why these two claims are not duplicate are persuasive.

Conclusion

10. Instant SEQ ID NO: 1 is free of the prior art. The closest match to the full length of SEQ ID NO: 1 is given in GenBank U85876, and is the 16S ribosomal RNA gene from P. glacincola. This sequence is 87% identical to instant SEQ ID NO: 1 over the full length of instant SEQ ID NO: 1. An alignment is provided with this office action (Sequence Alignment 1).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Wednesday, from 9:00 AM until 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Juliet C. Switzer

Primary Examiner

Art Unit 1634

December 23, 2005